

102491

**From:** Chan, Christina  
**Sent:** Wednesday, August 27, 2003 12:10 PM  
**To:** Cook, Lisa; STIC-Biotech/ChemLib  
**Subject:** RE: RUSH SEQUENCE SEARCH

Please rush. Thanks Chris

Chris Chan

TC 1600 New Hire Training Coordinator and SPE 1644  
308-3973  
CM-1, 9B19

-----Original Message-----

**From:** Cook, Lisa  
**Sent:** Wednesday, August 27, 2003 11:34 AM  
**To:** Chan, Christina  
**Subject:** RUSH SEQUENCE SEARCH

Good morning Christina,

Would you please approve the following  
rush sequence search for an amendment  
application.

Thanks,  
Lisa

Application Number: 09/845,738

Title: Biopolymer marker indicative of disease state  
having a molecular weight of 1562 Daltons.

Inventions: George Jackowski  
Brad Thatcher  
Tammy Vrees  
John Marshall

Earliest priority filing date: 4/30/01

Search Request: Sequence search including  
interference search for SEQ ID NO:1.

OFF

Searcher: \_\_\_\_\_  
Phone: \_\_\_\_\_  
Location: \_\_\_\_\_  
Date Picked Up: \_\_\_\_\_  
Date Completed: \_\_\_\_\_  
Searcher Prep/Review: \_\_\_\_\_  
Clerical: \_\_\_\_\_  
Online time: \_\_\_\_\_

TYPE OF SEARCH:  
NA Sequences: \_\_\_\_\_  
AA Sequences: \_\_\_\_\_  
Structures: \_\_\_\_\_  
Bibliographic: \_\_\_\_\_  
Litigation: \_\_\_\_\_  
Full text: \_\_\_\_\_  
Patent Family: \_\_\_\_\_  
Other: \_\_\_\_\_

VENDOR/COST (where applic.)  
STN: \_\_\_\_\_  
DIALOG: \_\_\_\_\_  
Questel/Orbit: \_\_\_\_\_  
DRLink: \_\_\_\_\_  
Lexis/Nexis: \_\_\_\_\_  
Sequence Sys.: \_\_\_\_\_  
WWW/Internet: \_\_\_\_\_  
Other (specify): \_\_\_\_\_



## UNITED STATES PATENT AND TRADEMARK OFFICE

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UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
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**\*BIBDATASHEET\*****CONFIRMATION NO. 3448**

Bib Data Sheet

SERIAL NUMBER 09/845,738	FILING DATE 04/30/2001  RULE	CLASS 436	GROUP ART UNIT 1641	ATTORNEY DOCKET NO. 2132.040
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## APPLICANTS

George Jackowski, Kettleby, CANADA;

Brad Thatcher, Toronto, CANADA;  
Tammy Vrees, Oakville, CANADA; Jason Yantha, Toronto, CANADA;  
John Marshall, Toronto, CANADA;

STIC search  
submitted  
LYCOOK 8/26/03  
☺

\*\* CONTINUING DATA \*\*\*\*\*

\*\* FOREIGN APPLICATIONS \*\*\*\*\*

IF REQUIRED, FOREIGN FILING LICENSE GRANTED \*\* SMALL ENTITY \*\*

\*\* 06/26/2001

Foreign Priority claimed 35 USC 119 (a-d) conditions met Verified and Acknowledged	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> Met after Allowance	STATE OR  COUNTRY CANADA	SHEETS  DRAWING 2	TOTAL  CLAIMS 35	INDEPENDENT  CLAIMS 6
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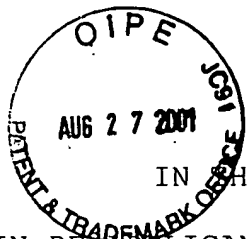
## ADDRESS

21917  
MCHALE & SLAVIN, P.A.  
2855 PGA BLVD  
PALM BEACH GARDENS, FL  
33410

## TITLE

Biopolymer marker indicative of disease state having a molecular weight of 1562 daltons

FILING FEE  RECEIVED 675	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:	<input type="checkbox"/> All Fees <input type="checkbox"/> 1.16 Fees ( Filing ) <input type="checkbox"/> 1.17 Fees ( Processing Ext. of time ) <input type="checkbox"/> 1.18 Fees ( Issue ) <input type="checkbox"/> Other _____ <input type="checkbox"/> Credit
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
IN RE APPLICANT

INVENTION

: Jackowski et al

: Biopolymer Marker Indicative of  
Disease State Having a Molecular  
Weight of 1562 Daltons

SERIAL NUMBER

: 09/845,738

FILING DATE

: April 30, 2001

EXAMINER

: N/A

GROUP ART UNIT

: 1743

OUR FILE NO.

: 2132.040

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To: The Commissioner of Patents and Trademarks  
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir or Madam:

Please enter the following amendment preliminary to  
examination on the merits, no new matter is added:

IN THE CLAIMS:

3. (New) A method for evidencing and categorizing at least one  
disease state comprising:

obtaining a sample from a patient;

conducting mass spectrophotometric analysis on said sample;  
evidencing and categorizing at least one biopolymer marker  
sequence or analyte thereof isolated from said sample; and,

comparing said at least one isolated biopolymer marker  
sequence or analyte thereof to the biopolymer marker sequence as  
set forth in claim 1;

wherein correlation of said isolated biopolymer marker and  
said biopolymer marker sequence as set forth in claim 1 evidences  
and categorizes said at least one disease state.

4. (New) The method of claim 3, wherein said step of evidencing  
and categorizing is particularly directed to biopolymer markers or  
analytes thereof linked to at least one risk of disease development  
of said patient.

5. (New) The method of claim 3, wherein said step of evidencing  
and categorizing is particularly directed to biopolymer markers or  
analytes thereof related to the existence of a particular disease  
state.

6. (New) The method of claim 3, wherein the sample is an  
unfractionated body fluid or a tissue sample.

7. (New) The method of claim 3, wherein said sample is at least one of the group consisting of blood, blood products, urine, saliva, cerebrospinal fluid, and lymph.

8. (New) The method of claim 3, wherein said mass spectrophotometric analysis is Surface Enhanced Laser Desorption Ionization (SELDI) mass spectrometry (MS).

9. (New) The method of claim 3, wherein said patient is a human.

10. (New) A diagnostic assay kit for determining the presence of the biopolymer marker or analyte thereof of claim 1 comprising:

at least one biochemical material which is capable of specifically binding with a biomolecule which includes at least said biopolymer marker or analyte thereof, and

means for determining binding between said biochemical material and said biomolecule.


11. (New) The diagnostic assay kit of claim 10, wherein said biochemical material or biomolecule is immobilized on a solid support.

12. (New) The diagnostic assay kit of claim 10 including:  
at least one labeled biochemical material.

13. (New) The diagnostic assay kit of claim 10, wherein said biochemical material is an antibody.

14. (New) The diagnostic assay kit of claim 12, wherein said labeled biochemical material is an antibody.

15. (New) The diagnostic assay kit of claim 10, wherein the sample is an unfractionated body fluid or a tissue sample.

 16. (New) The diagnostic assay kit of claim 10, wherein said sample is at least one of the group consisting of blood, blood products, urine, saliva, cerebrospinal fluid, and lymph.

17. (New) The diagnostic assay kit of claim 10, wherein said marker includes the sequence ID ITHRIHWESASLL and said biochemical material is at least one monoclonal antibody specific therefore.

✓ 18. (New) A kit for diagnosing, determining risk-assessment, and identifying therapeutic avenues related to a disease state comprising:

at least one biochemical material which is capable of specifically binding with a biomolecule which includes at least one biopolymer marker including the sequence ID ITHRIHWESASLL or an analyte thereof related to said disease state; and

means for determining binding between said biochemical material and said biomolecule;

whereby at least one analysis to determine a presence of a marker, analyte thereof, or a biochemical material specific thereto, is carried out on a sample.

19. (New) The kit of claim 18, wherein said biochemical material or biomolecule is immobilized on a solid support.

20. (New) The kit of claim 18 including:  
at least one labeled biochemical material.

21. (New) The kit of claim 18, wherein said biochemical material is an antibody.

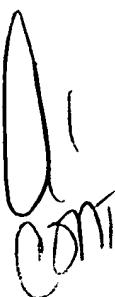
22. (New) The kit of claim 20, wherein said labeled biochemical material is an antibody.

23. (New) The kit of claim 18, wherein the sample is an unfractionated body fluid or a tissue sample.

24. (New) The kit of claim 18, wherein said sample is at least one of the group consisting of blood, blood products, urine, saliva, cerebrospinal fluid, and lymph.

25. (New) The kit of claim 18, wherein said marker includes the sequence ID ITHRIHWESASLL or at least one analyte thereof and said biochemical material is at least one monoclonal antibody specific therefore.

26. (New) The kit of claim 18, wherein said diagnosing, determining risk assessment, and identifying therapeutic avenues is carried out on a single sample.

 27. (New) The kit of claim 18, wherein said diagnosing, determining risk assessment, and identifying therapeutic avenues is carried out on multiple samples such that at least one analysis is carried out on a first sample and at least another analysis is carried out on a second sample.

28. (New) The kit of claim 27, wherein said first and second samples are obtained at different time periods.

29. (New) Polyclonal antibodies produced against the marker sequence ID ITHRIHWESASLL in at least one animal host.

30. (New) An antibody that specifically binds a biopolymer including the marker sequence ID ITHRIHWESASLL or at least one analyte thereof.



31. (New) The antibody of claim 30 that is a monoclonal antibody.

32. (New) The antibody of claim 30 that is a polyclonal antibody.

33. (New) A process for identifying therapeutic avenues related to a disease state comprising:

conducting an analysis as provided by the kit of claim 18; and

interacting with a biopolymer including the sequence ID

ITHRIHWESASLL or at least one analyte thereof;

whereby therapeutic avenues are developed.

34. (New) The process for identifying therapeutic avenues related to a disease state in accordance with claim 33, wherein said therapeutic avenues regulate the presence or absence of the biopolymer including the sequence ID ITHRIHWESASLL or at least one analyte thereof.

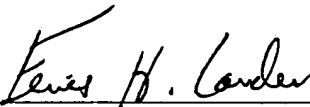
35. (New) A process for regulating a disease state by controlling the presence or absence of a biopolymer including the sequence ID ITHRIHWESASLL or at least one analyte thereof.

#### REMARKS

The above additions to the claims find basis in the original disclosure generally at page 12, lines 2 - 12, and at page 16, line 2 to page 18, line 10. Page 6, lines 5 - 20 refer to the use of the specific terms "analyte", "molecular fragmentation" and "fragment ions". By its definition within the specification, immunologic complexes and fragments thereof are therefore included. Page 28, lines 3 - 23 refer to the use of samples which are a variety of blood and blood products and their measurement. Page 29, line 4 refers to known immunoassay techniques and provides an article by Takahashi which is incorporated by reference (page 33, line 3). This article describes the standard use of obtaining more than one sample and at different time periods. Page 31, lines 6 - 8 refer to the use of polyclonal antibodies produced in an animal host. Page 14, lines 18 - 22 refer to the therapeutic avenues to be developed based on interactions observed such as within the complement system in order to regulate the progression of disease involving a form of a biopolymer. It is clear from these specific recitations and from the description of methods utilized to develop therapies based on the specific biopolymer disclosed that the

methods, types of kits and antibodies were fully contemplated by the inventor at the time of filing and were enabled by virtue of the disclosure as originally filed.

Respectfully submitted,

  
\_\_\_\_\_  
Ferris H. Lander  
Registration # 43,377

Date: August 10, 2001

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(561) 625-6575 (Voice)  
(561) 625-6572 (Fax)

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## UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
www.uspto.gov

**\*BIBDATASHEET\*****CONFIRMATION NO. 3448**

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John Marshall, Toronto, CANADA;

\*\* CONTINUING DATA \*\*\*\*\*

\*\* FOREIGN APPLICATIONS \*\*\*\*\*

IF REQUIRED, FOREIGN FILING LICENSE GRANTED \*\* SMALL ENTITY \*\*

\*\* 06/26/2001

Foreign Priority claimed 35 USC 119 (a-d) conditions met	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> Met after Allowance	STATE OR COUNTRY CANADA	SHEETS DRAWING 2	TOTAL CLAIMS 35	INDEPENDENT CLAIMS 6
Verified and Acknowledged	Examiner's Signature _____ Initials _____				

## ADDRESS

21917

MCHALE &amp; SLAVIN, P.A.

2855 PGA BLVD

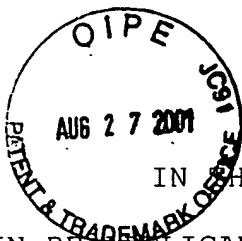
PALM BEACH GARDENS , FL

33410

## TITLE

Biopolymer marker indicative of disease state having a molecular weight of 1562 daltons

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RECEIVED 675		<input type="checkbox"/> 1.16 Fees ( Filing )
		<input type="checkbox"/> 1.17 Fees ( Processing Ext. of time )
		<input type="checkbox"/> 1.18 Fees ( Issue )
		<input type="checkbox"/> Other _____
		<input type="checkbox"/> Credit



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
IN RE APPLICANT

: Jackowski et al

INVENTION

: Biopolymer Marker Indicative of  
Disease State Having a Molecular  
Weight of 1562 Daltons

SERIAL NUMBER

: 09/845,738

FILING DATE

: April 30, 2001

EXAMINER

: N/A

GROUP ART UNIT

: 1743

OUR FILE NO.

: 2132.040

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To: The Commissioner of Patents and Trademarks  
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir or Madam:

Please enter the following amendment preliminary to  
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obtaining a sample from a patient;

conducting mass spectrophotometric analysis on said sample;  
evidencing and categorizing at least one biopolymer marker  
sequence or analyte thereof isolated from said sample; and,

comparing said at least one isolated biopolymer marker  
sequence or analyte thereof to the biopolymer marker sequence as  
set forth in claim 1;

wherein correlation of said isolated biopolymer marker and  
said biopolymer marker sequence as set forth in claim 1 evidences  
and categorizes said at least one disease state.

4. (New) The method of claim 3, wherein said step of evidencing  
and categorizing is particularly directed to biopolymer markers or  
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6. (New) The method of claim 3, wherein the sample is an  
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7. (New) The method of claim 3, wherein said sample is at least one of the group consisting of blood, blood products, urine, saliva, cerebrospinal fluid, and lymph.

8. (New) The method of claim 3, wherein said mass spectrophotometric analysis is Surface Enhanced Laser Desorption Ionization (SELDI) mass spectrometry (MS).

9. (New) The method of claim 3, wherein said patient is a human.

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at least one biochemical material which is capable of specifically binding with a biomolecule which includes at least said biopolymer marker or analyte thereof, and

means for determining binding between said biochemical material and said biomolecule.

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12. (New) The diagnostic assay kit of claim 10 including:

at least one labeled biochemical material.

13. (New) The diagnostic assay kit of claim 10, wherein said biochemical material is an antibody.

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17. (New) The diagnostic assay kit of claim 10, wherein said marker includes the sequence ID ITHRIHWESASLL and said biochemical material is at least one monoclonal antibody specific therefore.

✓ 18. (New) A kit for diagnosing, determining risk-assessment, and identifying therapeutic avenues related to a disease state comprising:

at least one biochemical material which is capable of specifically binding with a biomolecule which includes at least one biopolymer marker including the sequence ID ITHRIHWESASLL or an - analyte thereof related to said disease state; and



means for determining binding between said biochemical material and said biomolecule;

whereby at least one analysis to determine a presence of a marker, analyte thereof, or a biochemical material specific thereto, is carried out on a sample.

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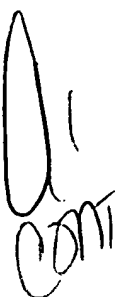
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33. (New) A process for identifying therapeutic avenues related to a disease state comprising:

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whereby therapeutic avenues are developed.

34. (New) The process for identifying therapeutic avenues related to a disease state in accordance with claim 33, wherein said therapeutic avenues regulate the presence or absence of the biopolymer including the sequence ID ITHRIHWESASLL or at least one analyte thereof.

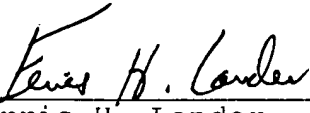
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Ferris H. Lander  
Registration # 43,377

Date: August 10, 2001

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